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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,631	02/12/2001	David Reginald Adams	040283/0182	9046

7590

04/14/2003

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EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

18

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/600,631

Applicant(s)

ADAMS ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-17 and 23-29 are currently pending in the instant application and are rejected under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-17, 23-28 and newly added claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 872447 and EP0194112 for the reasons essentially those as set forth in the Office Actions mailed 19 September 2002 and 7 March 2002. To wit it would have been obvious to substitute the prior art compounds of GB 872447 which are useful as a sedative and an antispasmodic agent when faced with the secondary reference of EP 0194112, which discloses substituted structurally similar compounds pharmacologically active against CNS disorders.

Response to Arguments

Applicant's arguments filed 21 January 2003 have been fully considered but they are not persuasive. Applicant argues that the declaration under 37 CFR 1.132, by Nathaniel Julius Monck dated 2 February 2003, provides evidence to one of skill in the art that the invention provides unexpected results that would not be predicted based on the prior art. This argument is not persuasive for the following reasons:

The declaration does not provide a clear and convincing showing of unobvious and unexpected results of the invention as instantly claimed over the prior art.

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First, the declaration is not commensurate in scope with the instantly claimed invention (comparing only one compound from under the instant claims) and even if found convincing would only provide evidence of unexpected results for the compound of example 20 which is the compound of formula 1 wherein R1 is substituted with trifluoromethyl. The evidence provided in the declaration shows the dose required of a vehicle, example 20 (of the instant specification) and 1-carbamoyl-3-phenylazetidine (prior art compound) to achieve a specific effective dose (ED50). The ED50 of example 20 at 15 mg/kg s.c. is 25.5 with a confidence of 22.8-27.4, and the ED50 of 15 mg/kg s.c. of the prior art compound (1-carbamoyl-3-phenylazetidine) is 22.1 with a confidence of 19.0-25.6. The confidence limits of the ED50 values of the compared compounds overlap and do not provide clear and convincing evidence that applicants example 20 has a more significant effect than the prior art compound since it appears from the data provided that a dose of 15 mg/kg s.c. of either example 20 or the prior art compound could result in the same ED50. The declaration states on page 3, lines 8-10 of paragraph No. 10, that the experiment was not designed to test the difference in the ED50 values of example 20 and the prior art compound. It is therefore not clear what the test was designed to show since the only data provided is the dose and ED50 value. Applicant provides an asterisk (*) to delineate a significant effect, however data supporting this significant effect is not provided anywhere in the declaration. The declaration also states in paragraph No. 10 that at 15 mg, Example 20 is significantly different from the vehicle and therefore active, whereas the prior art compound is not significantly different and therefore not active. Again, the confidence limits of the data

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provided does not support a significant difference between Example 20 and the prior art compound. The declaration only provides an asterick and a statement about the significant effect of the compound of example 20. Without data supporting this significant effect (*) the declaration cannot be considered as providing a sufficient showing of unobvious and unexpected results.

Second, the declaration which states on page 3, lines 11-12 of paragraph No. 10, that the prior art compound (1-carbamoyl-3-phenylazetidine) is not significantly different from the vehicle and is therefore not active goes against the teachings the instant specification, which discloses that compounds of the formula (1) wherein R1 is aryl, such as phenyl (page 3) (with a preference towards substituted or unsubstituted phenyl (page 5)), that are useful for the treatment of CNS disorders (page 8). The specification does not support a difference in the use of the compounds of the formula (I), i.e. all compounds are considered useful for the treatment of CNS disorders, so the specification does not provide a basis for now saying that one of the compounds under the genus of formula I (1-carbamoyl-3-phenylazetidine) is now, unexplainably, not active. Again, the statement in the declaration that 1-carbamoyl-3-phenylazetidine is not active is contradictory to the teachings of the specification. Therefore, the evidence presented in the declaration can be given little weight. Also, since the declaration is not commensurate in scope with the claimed invention it now clouds the judgement on all other uncomparred (untested) compounds (i.e. compounds wherein R1 is substituted with other than trifluoromethyl) as to what compounds would be useful for the treatment of CNS disorders.

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Applicants arguments filed 21 January 2003 have been full considered and are persuasive in regards to the 35 U.S.C. 102(b) rejection. Applicant argues that one of skill in the art would use the term "substituted aryl" to refer to an aryl ring wherein one or more of the hydrogen atoms has been replaced by some other group. Based on this argument and the list of possible substituents on pages 3-5, the 35 U.S.C. 102(b) rejection of claims 1, 2 and 23-28 is no longer maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

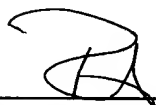
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



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